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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,293	04/29/2006	Zhiqiang Gao	4276-103	8043

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
KAUR, GURPREET	
ART UNIT	PAPER NUMBER
1795	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,293	GAO ET AL.	
	Examiner	Art Unit	
	GURPREET KAUR	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

1. Claims 1-26 are pending and are being examined.

Response to Amendment

2. Applicant's amendment of 12/04/2009 does not render the application allowable.

Status of the Rejections

3. The objection to the claims 1, 5 and15 has been withdrawn in view of Applicant's amendment.

35 U.S.C. 112, first paragraph rejection is withdrawn in light of the amendments to claim 5.

35 U.S.C. 112, second paragraph rejection is withdrawn in light of the amendments to claims 16 and 21.

The previous rejections are same as presented before.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6-19 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Willner et al. (U.S. Pat. No. 6,214,205).

Regarding claim 1, Willner et al. teaches the method of electrochemical determination of the presence of the analyte in the liquid medium with a detecting electrode (electrode) (see abstract and col. 4, lines 16-20), the method comprising:

(a) immobilizing capture molecule (one recognition pair, antigen-antibody) which binds with analyte on the electrode (see col. 4, lines 19-21 and col. 3, lines 38-44);

(b) contacting electrode with liquid medium containing analyte (see col. 4, lines 25-30);

(c) allowing the analyte in the liquid medium to bind with the capture molecule (immobilized member) to form pair of complexes, the complexes are between the immobilized member and the analyte on the surface of the electrode to form a first layer (monolayer) on the surface of the electrode (see col. 4, lines 26-30, 64-67 over to col. 5 and col. 12, lines 32-34);

(d) contacting the electrode with electrochemical activator (first redox molecule), the first redox molecule is capable of transferring electrons to allow the detection of analyte upon complex formation (see col. 4, lines 1-24 and figures 3A-3B), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to form a second layer (electrochemical activator layer) on the electrode. Furthermore, both the second layer and first layer are conducting since the electron transfer occurs between the layers to detect the analyte (see figures 13A-13C);

(e) contacting the electrode with an agent (second redox molecule) to transfer electron to or from the electrochemical activator from or to the electrode to give to an

electrical response to indicate the presence of the analyte in the medium (see col. 4, lines 35-40), and ;

(f) detecting the analyte by comparing the result of electrical current (electrolytic oxidation of glucose) with that of control current (no electrolytic oxidation of glucose (see figures 3A-3B).

5. Regarding claims 6, 7, and 8, the agent (second redox molecule) is an enzyme (glucose oxdiase) capable of transferring electron to and from the electrochemical activator (see col. 15, lines 39-47).

6. Regarding claims 9-11, capture molecules (recognition pair, oligonucleotide-oligonucletotide) which bind with analyte (oligonucleotide) on the electrode (see col. 4, lines 19-21 and col. 3, lines 38-44). It is well know in the art an oligonucleotide is a short nucleic acid polymer.

7. Regarding claims 12-16, the recognition pair, oligonucleotide-oligonucleotide has a complementary sequence (see col. 3, lines 41-45), it is inherent a complementary sequence of oligonucleotide recognition pair contains single strand nucleic acid with a pre-defined sequence. Willner et al. further teaches a recognition pair comprised of oligonucleotide-protein, wherein the analyte is the protein and capture molecule is oligonucleotide capable of binding to protein (see col. 3, lines 41-45).

8. Regarding claim 17, the electrode is soaked in the blocking agent (cystamine) as an preliminary step before the application of analyte (see col. 13, lines 22-38).

9. Regarding claim 18, Willner et al. teaches the method of electrochemical determination of the presence of the analyte in the liquid medium with a detecting electrode (electrode) (see abstract and col. 4, lines 16-20), the method comprising:

(a) immobilizing capture molecule (one recognition pair, antigen-antibody) which binds with analyte on the electrode (see col. 4, lines 19-21 and col. 3, lines 38-44);

(b) contacting electrode with liquid medium containing analyte (see col. 4, lines 25-30);

(c) allowing the analyte in the liquid medium to bind with the capture molecule (immobilized member) to form pair of complexes, the complexes are between the immobilized member and the analyte on the surface of the electrode to form a first layer (monolayer) on the surface of the electrode (see col. 4, lines 26-30, 64-67 over to col. 5 and col. 12, lines 32-34);

(d) contacting the electrode with electrochemical activator (first redox molecule), the first redox molecule is capable of transferring electrons to allow the detection of analyte upon complex formation (see col. 4, lines 1-24 and figures 3A-3B), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to form a second layer (electrochemical activator layer) on the electrode. Furthermore, both the second layer and first layer are conducting since the electron transfer occurs between the layers to detect the analyte

(see figures 13A-13C) and Willner et al. further indicate that a recognition pair is an enzyme-substrate (see col. 3, lines 40-45 and figure 3A) therefore inherently a capture molecule (enzyme) is capable of transferring electrons to or from the electrochemical activator or to the electrode and ;

(e) measuring electric current and detecting the analyte by comparing the result of electrical current with that of control current (see figures 3A-3B).

10. Regarding claim 19, Willner et al. teaches an electrode arrangement (system) comprising a detection electrode (electrode) for the detection of the analyte (see col. 8, lines 53-54 and col. 4, lines 16-20),

(a) electrode covered with monolayer comprising complexes (binding couple) between a capture molecule (recognition pair, antigen-antibody) which binds with analyte (see col. 8, lines 53-58 and col. 4, lines 26-30 and col. 3, lines 38-44);

(b) the electrode is immobilized with electrochemical activator as second layer (first redox molecule layer) and the first redox molecule is capable of transferring electrons to allow the detection of analyte upon complex formation (see col. 4, lines 1-24 and figures 3A-3B), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to allow transfer of electrodes. Furthermore, both the second layer and the first layer are conducting since the electron transfer occurs between the layers to detect the analyte (see figures 13A-13C)

11. Regarding claims 23 and 24, the agent (second redox molecule) is an enzyme (glucose oxdiase) capable of transferring electron to and from the electrochemical activator (see col. 15, lines 39-47). The agent (second redox molecule) is bound with first redox molecule to form a bilayer (see col. 10, lines 21-27 and figures 4A and 4B).

12. Regarding claim 25, the electrode arrangement (system) is a biosensor since it detects analyte in the biological fluid (see col. 4, lines 44-45).

13. Regarding claim 26, Willner et al. teaches an electrode arrangement (system) for the detection of the analyte in biological fluid (see col. 8, lines 53-54 and col. 4, lines 16-20 and 44-45),

(a) a detection electrode (20) (see figure 3A);

(b) electrode covered with monolayer comprising complexes (binding couple) between a capture molecule (recognition pair, antigen-antibody) which binds with analyte (see col. 8, lines 53-58 and col. 4, lines 26-30 and col. 3, lines 38-44);

(c) the electrode is immobilized with electrochemical activator as second layer (first redox molecule layer) and the first redox molecule is capable of transferring electrons to allow the detection of analyte upon complex formation (see col. 4, lines 1-24 and figures 3A-3B), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to allow transfer of electrodes. Furthermore, both the second layer and the first layer are conducting since

the electron transfer occurs between the layers to detect the analyte (see figures 13A-13C);

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 2-4 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willner et al. (U.S. Pat. No. 6,214,205) as applied to claims 1, 6-19 and 23-26 above, and further in view of Zhiqiang et al. (Electrodeposition of Redox Polymer and Co-Electrodeposition of Enzymes by Coordinative Crosslinking, *Angew.Chem.Int. Ed.* 2002, 41, 810-813).

Regarding claims 2-4 and 20-22, Willner et al. teaches electrochemical activator is ferrocene monocarboxylic acid which inherently comprises iron metal ions (see col.

16, lines 6-8) but Willner et al. does not teach electochemical activator is a polymeric redox polymer that comprises metal ions.

However, Zhiqiang et al. teaches a polymeric redox polymer deposit on the electrodes which further conducts electron transfer to oxidized/reduced substrates of the enzyme (see page 810, col. 1 paragraph 1 and col. 2, paragraph 1). The redox polymers are water soluble and readily bound to proteins and enzymes (see page 812 paragraph 1).

Zhiqiang et al. further teaches that polymeric redox polymer comprises osmium metal ions coordinated with the ligands (see scheme 1 on page 811).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to substitute polymeric redox polymer activator of Zhiqiang et al. with the Willner et al. electrochemical activator because polymeric redox polymer is water soluble and readily bound to proteins and enzymes to co-electrodeposit enzymes.

15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willner et al. (U.S. Pat. No. 6,214,205) and Zhiqiang as applied to claim 2 above and further in view of Feldman et al. (U.S. Pat. No. 6,299,757).

Regarding claim 5, Willner et al. and Zhiqiang does not teach electrochemical activator comprises poly(vinyl ferrocene) or its derivative.

However, Feldman et al. teaches a redox mediator comprised of poly(vinyl ferrocene) to increase swelling of the redox polymer in water (see col. 21, lines 20-24 and col.22, lines 5-16).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to substitute redox mediator comprised poly(vinyl ferrocene) of Feldman et al. with the Willner et al. electrochemical activator because the use of Feldman et al. activator increase swelling of the redox polymer in water.

Response to Arguments

Applicant's arguments filed 12/04/2009 have been fully considered but they are not persuasive.

For claims 1, 18, 19 and 26, examiner has included Figures 13B and 13C in the rejection to illustrate that current is detected when both the layers (first and second layers) are present.

Examiner does recognize the difference between the disclosure of application and the prior art reference, however examiner respectfully disagree with the applicant's arguments, as the claimed invention and the prior art reference teaches the same invention. Instant claim 1 claims a method of detecting the analyte based on formation of first and second layer. Willner teaches the formation of first layer i.e. immobilizing the electrode with capture molecule and analyte to form complexes and second layer i.e. contacting the electrode with first redox molecule (see col. 4, lines 1-24, 26-30 and 64-67). Willner further teaches the current can be detected when both the first and second layers are present on the electrode (see figures 13A-13C).

Arguments regarding claims 2-17 and 20-25 are moot based on their dependence on claims 1 and 19 respectively.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is (571)270-7895. The examiner can normally be reached on Monday-Friday (Alternate Friday Off), 8:00-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

/G. K./
Examiner, Art Unit 1795
2/22/2010